

REMARKS

Applicants respectfully request entry of the Amendment filed April 16, 2009, in view of the RCE filed concurrently herewith.

I. Request for Interview

Applicants representative attempted to contact the Examiner to request an Interview, but has not received a return phone call as of the filing date of this Amendment. The Examiner is requested to contact the undersigned upon receipt of this Amendment to schedule an Interview.

II. Response to Advisory Action

In the Advisory Action dated May 15, 2009, the Examiner indicates that the Amendment filed April 16, 2009 was not entered because the amendments to the claims raise an issue of new matter. Specifically, in the “note” the Examiner asserts that the amendment of claim 10 introduces new matter, support for which can not be found in the specification.

However, as indicated in the Amendment filed April 16, 2009, support for the amendment to claim 10 is found in the paragraph bridging pages 29-30 of the specification as filed, which corresponds to paragraph [0065] of the published application, Pub. No. 2008/0039516. The disclosure states:

In accordance with the invention, the phrase “containing” means that solifenacin or a salt thereof as the active pharmaceutical ingredient is in mixture with the inhibitor of amorphous preparation. Preferably, solifenacin or a salt thereof is in contact with an inhibitor of amorphous preparation so that solifenacin or a salt thereof is distributed in a state of mixture. *As in the case of using a pharmaceutical composition as a coating agent of solifenacin formulation wherein the active pharmaceutical ingredient, solifenacin or a salt thereof, is not in contact with or in mixture with such inhibitor of amorphous preparation so that it exists in a localized state (for example the inhibitor of amorphous*

preparation in accordance with the invention (PEG)),
pharmaceutical preparations for example at a state *such that
solifenacin or a salt thereof is not in physical contact with a
inhibitor of amorphous preparation in an intermediate layer using
other additives and the like are excluded* (emphasis added).

This disclosure clearly refers to an embodiment wherein crystalline and amorphous solifenacin or a crystalline and amorphous salt thereof is mixed with, or in contact with, an inhibitor of an amorphous preparation and also excludes an embodiment wherein the solifenacin or salt thereof is coated with a coating agent and the inhibitor of an amorphous preparation is contained in the coating layer and is not mixed with or in contact with, the solifenacin or salt thereof, which is contained in another layer. Thus, the previous amendment to claim 10 as in the Amendment filed April 16, 2009, is supported by the specification as filed and is not new matter.

Notwithstanding the above, claim 10 is amended herein to recite that the solifenacin is “not in contact with or in mixture with the inhibitor of amorphous preparation” to further clarify the claimed invention. The amendment to claim 10 is also supported by the disclosure at the paragraph bridging pages 29-30 and does not raise an issue of new matter.

Additionally, in the Advisory Action, the Examiner states that the rejection of claims 10, 12 and 17, for obviousness double patenting over Umejima et al U.S. 2008/0103171 is maintained for the reasons of record. The rejections of claims 10, 12 and 17 under 102(e) as being anticipated by Slatter et al (U. S. 2004/0138523), Fraser et al (U. S. 2004/0198822), Saito et al (U. S. 2005/0181031) and Fraser et al (U. S. 2005/0239890) are also maintained for the reasons of record.

Applicants respectfully defer responding to the obviousness-type double patenting rejection and request that the rejection be held in abeyance.

Applicants further submit that the present invention as recited in the amended claims is not anticipated by the cited references for the reasons set forth in the Amendment filed April 16, 2009, which are incorporated herein by reference.

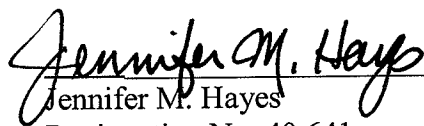
Accordingly, withdrawal of the anticipation rejections based on each of Slatter et al, Fraser et al, Saito et al and Fraser et al is respectfully requested.

III. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,


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